REMARKS

Claims 1-26 are pending in this application. By the Preliminary Amendment, claim 6 is amended and new claims 15-26 are added. Support for the amendment can be found in the specification and the original claims as filed. No new matter is added.

The attached Appendix includes a marked-up copy of each rewritten claim (37 C.F.R. §1.121(c)(1)(ii)).

I. Response to Restriction Requirement

In a Restriction Requirement mailed May 19, 2003 restriction was required between Groups I-IV.

In response to the Requirement, Applicants provisionally elect Group II, claims 4, 5 and 11-13, as well as new claims 15-26, drawn to a method for testing a biological sample wherein the protein sequence of the HIV-2 protease is investigated by measuring the nucleotide sequence of the protease gene, with traverse.

A. Lack of Unity of Invention Has Not Been Demonstrated

Applicants respectfully assert that the Requirement is improper under the rules of practice in PCT national stage applications, because the appropriate unity of invention standards have not been properly applied by the Patent Office. In PCT national stage applications, the Examiner may issue a restriction-type Requirement if no unity of invention exists. However, the Examiner must state why there is no "single general inventive concept." See MPEP §1893.03(d). Therefore, a single application may include one invention, or more than one invention if the inventions are "linked as to form a single general inventive concept." Id. (emphasis added). If multiple inventions are included in the application, they are deemed to be linked if there exists a "technical relationship among the inventions that involves at least one common or corresponding special technical feature." Id.

Unity of invention exists when there is a technical relationship among the claimed inventions involving one or more special technical features defining a contribution made over the prior art. See, MPEP §1850. The unity determination is made based on the contents of the claims. "[U]nity of invention has to be considered in the first place only in relation to the independent claims and not the dependent claims. . . . If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent itself contains a further invention." Id.

B. Unity of Invention Exists as Between Groups I & II

The Restriction Requirement asserts that the inventions of Groups I and II are different because they are testing a protein sequence versus a nucleic acid sequence, respectively, and therefore the starting materials, reagents and method steps are different. Applicants respectfully submit that the Restriction Requirement between Group I and II is improper and should be withdrawn.

Starting with the independent claim 1 and 8 of Group I, they are both drawn to a method for testing a biological sample that includes investigating the presence of mutations in the protein sequence of the HIV-2 protease. The Restriction Requirement recognizes that claims 1 and 8 satisfy the requirement of unity of invention by including the claims together in Group I. In addition, the Restriction Requirement fails to provide any evidence of record to support a finding that claims 1 and 8 do not define over the prior art. The Restriction Requirement does not identify any prior art to maintain a contention that the special technical features of claims 1 and 8 do not avoid the prior art. Therefore, regarding independent claims 1 and 8, unity of invention exists.

Second, all of the claims of Group II, i.e., claims 4, 5, 11-13, as well as new claims 15-26, depend from either claims 1 or 8. Thus, since the independent claims avoid the prior art and

satisfy the requirement of unity of invention, "no problem of lack of unity arises in respect of any claims that depend on the independent claims." For this reason alone, the Restriction Requirement between Groups I and II should be withdrawn.

The subject matter of claim 1 encompasses a method to test a biological sample for resistant strains of HIV-2 by investigating mutations in the protein sequence of the HIV-2 protease. All of the technical features of claim 1 define the subject matter over the prior art. Dependent claims 4-6 include an additional feature that further defines how that protein mutation is detected, i.e., by testing the nucleotide sequence. Thus, claims 4-6 also contain the same technical features as claim 1. In the same way, the technical features of claim 8 are defined over the prior art. Dependent claims 11-13 are comparable to claims 4-6 and feature a means to further investigate protein mutations. The investigation of mutations in a nucleotide sequence merely provides another means to investigate the mutations in a protein sequence. Any distinction between the two methods would be arbitrary.

Accordingly, for this reason also, the Restriction Requirement between Groups I and II should be withdrawn.

C. Group III

The Preliminary Amendment submitted herewith amends claim 6 to depend from claim 4. Amended claim 6 is directed to a method to detect a mutation of the protein sequence by detecting a corresponding mutation in the nucleotide sequence of the gene using sequencing techniques. As amended, claim 6 compares to claim 5 of Group II. Applicants respectfully submit that amended claim 6 contains all of the limitations of claim 4 and belongs in Group II, thus rendering moot this Restriction Requirement.

D. Group IV

As detailed above, the method of claims 4 and 11 include special technical features defined over the prior art. The probes of claims 7 and 14 are essential tools for performing at

least one embodiment of the methods defined in claims 4 and 11. Thus, the probes belong to the same invention as the methods of Group II. Accordingly, the Restriction Requirement between Groups II and IV should be withdrawn.

E. Conclusion

Thus, because the Office Action has not properly demonstrated an absence of unity of invention under the rules, and because unity of invention in fact exists between all of Groups I-IV, the Restriction Requirement is improper and must be withdrawn. Reconsideration and withdrawal of the Restriction Requirement are respectfully solicited.

II. Response to Election of Specific Mutation

The Restriction Requirement requires the election of a specific mutation to be examined. In response, Applicants have elected the mutation at position 90 with traverse. At least claims 1-7, 15 and 26 read on the elected subject matter.

Applicants traverse this election requirement on the ground that generic claims 1 is not so broad as to place an undue burden on the Patent Office to search and examine all of the mutations. Applicants respectfully assert that a search and examination of the entire application could be conducted without undue burden on the Examiner, thus avoiding delay and expense to Applicants.

Applicant further understands, however, that upon search, examination and allowance of the elected mutation, search and examination will continue as to the non-elected mutations within the scope of the generic claims.

Respectfully submitted,

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Date: June 19, 2003

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